APR 15 2013



# Section 5 510(k) Summary per 21 CFR §807.92 (c)

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| **Submitter's Name and Address** | Boston Scientific Corporation<br>47215 Lakeview Boulevard<br>Fremont, CA 94538 |
| **Contact Name and Information** | Eric Elliott<br>Regulatory Affairs Specialist<br>Tel: 510.624.1314<br>Fax: 510.624.2569<br>E-mail: Eric.Elliott@bsci.com |
| **Date Prepared** | November 20th, 2012 |
| **Trade Name** | OptiCross™ Coronary Imaging Catheter |
| **Common Name** | Diagnostic Intravascular Catheter<br>Ultrasound Transducer |
| **Classification Name** | Catheter, Ultrasound, Intravascular (OBJ) has been classified as Class II per 21 CFR 870.1200<br>Transducer Ultrasonic (ITX) has been classified as Class II per 21 CFR 892.1570. |
| **Predicate Device** | Atlantis SR Pro2/iCross K111043 04 August 2011 |
| **Description of Device** | OptiCross™ is a short-rail 40 MHz IVUS imaging catheter. It is compatible with a 0.014" guidewire, and at a minimum, a 5F guide catheter (≥ 0.058").<br>OptiCross is intended for use with the BSC iLab™ imaging console (K072517) and Boston Scientific's next generation motor drive unit, MDU5 PLUS™. When used together, the catheter, motor drive unit (MDU), and iLab equipment form a complete imaging system that allows for ultrasonic examination of coronary intravascular pathology.<br>The catheter consists of two main components: the catheter body and the imaging core. |

**Device Description, continued**

The catheter body consists of four sections: the telescope assembly, proximal shaft, distal shaft, and the distal guidewire lumen. The proximal shaft, distal shaft, and distal guidewire lumen comprise the usable length of the catheter (135 cm). The proximal telescoping section remains outside of the guide catheter.

The distal guidewire lumen (1.6 cm) is used to track the catheter along the guidewire and incorporates a radiopaque marker band (0.5 cm from the distal tip). The distal shaft serves as a flexible and acoustically transparent imaging window. The proximal shaft provides pushability to the distal imaging window and serves as a lumen to the imaging core. Two insertion markers are located on the proximal shaft (90 and 100 cm from the distal tip). These markers facilitate estimation of catheter position relative to the distal tip of the guide catheter.

The telescope assembly allows the imaging core to be advanced and retracted up to 15 cm. The corresponding movement of the transducer occurs from the proximal end of the guidewire lumen to the proximal end of the imaging window. The telescoping shaft includes 16 incremental markers for lesion length assessment (1 cm apart); the 5-cm, 10-cm, and 15-cm markers are distinct. The outer surface of the catheter body also employs a hydrophilic coating to enhance lubricity and promote deliverability (distal 23 cm).

The imaging core consists of a proximal hub assembly and a rotating drive cable that houses a piezoelectric (PZT) transducer at the distal imaging window. The hub assembly (1) provides an electro-mechanical interface between the catheter and the motor drive unit and (2) incorporates a one-way check valve that is used to flush the interior of the catheter body. The catheter must be flushed with heparinized saline prior to use, as this provides the acoustic coupling media required for ultrasonic imaging.

The drive cable and PZT transducer rotate independently of the sheath assembly to provide 360° image resolution. The transducer converts electrical impulses sent by the motor drive in to transmittable acoustic energy. Reflected ultrasound signals are converted back to electrical impulses, returned to the motor drive unit, and are ultimately processed by the iLab equipment for visualization.

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**Inended Use/Indications for Use**

This catheter is intended for ultrasound examination of coronary intravascular pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.

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| **Device Technoogy Characteristics and Comparison to Predicate Device** | The OptiCross™ Coronary Imaging Catheter maintains the same fundamental scientific technology and operating principles as the predicate device, iCross. In addition, the shelf-life, packaging configuration, sterilization methodology, and indications for use remain unchanged.<br><br>The OptiCross Coronary Imaging Catheter incorporates new design features intended to enhance deliverability, reliability, and overall ease of use when compared to iCross™ (K111043).<br><br>Modifications with respect to the predicate device include: a new hub interface with the motor drive unit, an optimized proximal to distal shaft transition, reductions to proximal sheath profile and the distance between the transducer and distal tip, a narrower distal housing profile and transducer aperture, as well a narrower imaging window and guidewire exit port (crossing profile). In addition, 16 incremental markers (1 cm apart) have been added to the male telescope tube to aid in lesion length assessment. Material changes have been made to the hub seal, male telescope tube, proximal shaft, anchor housing, distal tip, catheter strain reliefs, potting and distal housing adhesives, and also include utilization of lead-free solders and flux.<br><br>In support of a substantial equivalence determination, Boston Scientific has compared and evaluated the material and design differences between the subject and predicate device.<br><br>Non-clinical performance evaluations, as described below, indicate that the subject device is substantially equivalent to, and at least as safe and effective as the predicate device (iCross). |

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| **Non-Clinical Performance Data** | Determination of substantial equivalence is based on an assessment of non-clinical performance data.<br><br>Non-clinical data includes bench-top performance evaluations, packaging validation, biological safety, and acoustic output testing.<br><br>Bench Testing:<br><br>Bench testing was performed to evaluate physical integrity, functionality, and performance of the catheter. Performance criteria includes deliverability, crossability, guide catheter compatibility, lubricity, retraction capability, image resolution, image penetration, non-uniform rotational distortion, image artifact, measurement accuracy, pullback reliability, general imaging capabilities, dimensional requirements, visibility under fluoroscopy, interface with ancillary devices, environmental requirements, user interface requirements, catheter robustness and simulated use structural integrity.<br><br>Biological Safety Testing:<br><br>The OptiCross™ Coronary Imaging Catheter was subjected to a series of biocompatibility tests in accordance with ISO 10993-1 (including genotoxicity), microbial assessments including bioburden and endotoxin, pyrogenicity, and sterility assurance.<br><br>Acoustic Output Testing:<br><br>Acoustic Output was evaluated in accordance with FDA Guidance, *Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers (September 9, 2008)*. Acoustic Output test results for the OptiCross™ Coronary Imaging Catheter are below the FDA Track 1 limits.<br><br>Packaging Validation:<br><br>The integrity of the packaging configuration was tested in accordance with ISO 11607-1 and ISO 11607-2. Testing was conducted on fully packaged units after subjected to electron beam sterilization, climatic conditioning, and distribution challenge conditioning.<br><br>Conclusion:<br><br>Non-clinical performance evaluations, as described above, indicate that the subject device is substantially equivalent to, and at least as safe and effective as the predicate device, iCross™ (K111043). |
| **Clinical Performance Data** | Not applicable; determination of substantial equivalence is based on an assessment of non-clinical performance data. |

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| **Conclusion** | New design features incorporated by the OptiCross™ Coronary Imaging Catheter do not affect scope of the intended use/indications for use, nor do they raise new concerns regarding safety or efficacy with respect to the predicate device.<br><br>As the indications for use and fundamental scientific technology have not changed, non-clinical performance data supports a determination that the subject device, OptiCross™, is substantially equivalent to the predicate device, iCross™(K111043); and that it is at least as safe and effective for its intended use. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

April 15, 2013

Boston Scientific Corporation
c/o: Eric Elliot
Sr. Director, Regulatory Specialist
47215 Lakeview Boulevard
Fremont, CA 94538

Re: K123621
Trade Name: OptiCross 40MHz Coronary Imaging Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II
Product Code: OBJ
Dated: February 28, 2013
Received: March 5, 2013

Dear Mr. Eric Elliot:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, Misbranding by reference to premarket notification (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htmfor the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

K123621

## Indications for Use

510(k) Number (if known): _____

Device Name: OptiCross™ Coronary Imaging Catheter

Indications for Use:

This catheter is intended for ultrasound examination of coronary intravascular pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S
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